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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,243	06/15/2001	Nils Carlin	CARL3003/REF	7055

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06/05/2002

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 06/05/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/868,243

Applicant(s)

Carlin et al.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 15, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 ~~is~~are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ ~~is~~are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 6) ☐ Other:

Serial Number: 09/868,243
Art Unit: 1645

DETAILED ACTION

Priority

- 1) The instant application is a 371 of PCT/SE99/02306, filed 12/09/1999 and claims foreign priority to application, 9804415-9, filed 12/18/1998 in Sweden.

Status of Claims

- 2) Claims 1-4 are pending and are under examination in this application.

Information Disclosure Statement

- 3) Acknowledgment is made of Applicants' Information Disclosure Statement filed 96/15/01 (paper no. 2). The information referred to therein has been considered and a signed copy of the same is attached to this Office Action (paper no. 3).

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

- 4) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

- 5) Claims 1-4 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 1 is vague in the recitation "an vehicle", because it is unclear what is encompassed in this limitation. It is suggested that Applicants replace the recitation with --a physiologically acceptable vehicle-- in claim 1. With this amendment, Applicants should delete the recitation "physiologically acceptable" in line 3 of claims 2 and 4.

(b) Claim 1 is vague and indefinite in the recitation "defined amount" (see line 2). This is a relative term and it is unclear what amount qualifies as a defined amount. Clarification/correction is requested.

(c) Claim 1 is confusing in the recitation "vaccine composition is purified from possible heat stable enterotoxin", as opposed to the antigens present in the vaccine composition being purified from heat stable enterotoxin. Clarification/correction is requested.

Serial Number: 09/868,243

Art Unit: 1645

(d) Claims 2-4, which depend directly or indirectly from claim 1, are also rejected under 35 U.S.C § 112, second paragraph, as being indefinite, because of the indefiniteness or vagueness identified above in the base claim.

Objection(s)

6) Claims 1 and 4 are objected to for the following reasons:

(a) In claims 1-4, for clarity, it is suggested that Applicants insert the preceding article --An-- prior to the recitation “[o]ral vaccine” (see line 1).

(b) In line 1 of claim, for clarity, it is suggested that Applicants replace the recitation “enterotoxigenic *E. coli* caused diarrhea” with --diarrhoea caused by enterotoxigenic *E. coli*--.

(c) It is unclear what purpose does the recitation “possible” serve in line 6 of the claim. It is suggested that Applicants delete this limitation since it appears to be unnecessary.

(d) Claim 4 is objected to for the grammatically incorrect recitation “..amount..... are” (see lines 1 and 2).

(e) Claim 1 is objected to for the grammatically incorrect recitation “an vehicle” (see line 6).

Relevant Prior Art

7) The prior art made of record and not relied upon in any of the rejections is considered pertinent to Applicants’ disclosure:

- Cassels *et al.* (WO 96/38171) teach raising antibodies using as immunogen a consensus peptide of 36 amino acids which induces antibodies against the proteins of all members of the *E. coli* family CS4-CFA/1 (see abstract).

- Cassels *et al.* (US 5,914,114) discloses a consensus peptide of *E. coli* CS4-CFA/1 family of proteins (see Examples 1 and 7).

Remarks

8) Claims 1-4 stand rejected.

9) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the

Serial Number: 09/868,243
Art Unit: 1645


Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which is able to receive transmissions 24 hours a day and 7 days a week.

10) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached from Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

June, 2002


S. DEVI, PH.D.
PRIMARY EXAMINER